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PATENT IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Peter Krulevitch, et al.	Docket No. :	IL-10896
Serial No. :	09/992,248	Art Unit :	3762
Filed :	11/16/2001	Examiner :	Jeffrey R. Jastrzab
For :	FLEXIBLE ELECTRODE ARRAY FOR ARTIFICIAL VISION		

TRANSMITTAL OF APPELLANTS' BRIEF ON APPEAL
(PATENT APPLICATION - 37 CFR 192)

Transmitted herewith in **duplicate** is the **APPELLANTS' BRIEF ON APPEAL** in this application with respect to the Notice of Appeal filed on March 3, 2006.

The item(s) checked below are appropriate:

1. **STATUS OF APPLICANT**
   This application is on behalf of
   ☐ other than a small entity.
   ■ a small entity.
   A verified statement
   ☐ is attached
   ■ already filed.

2. **FEE FOR FILING APPEAL BRIEF**
   Pursuant to 37 CFR 1.17(e) the fee for filing the Appeal Brief is:
   ■ small entity $250.00
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☐ Applicant petitions for an extension of time under 37 CFR 1.136

Calculation of extension fee (37 CFR 1.17(a)-(d)):

	Total months requested	Fee for other than small entity	Fee for small entity
☐	one month	$120.00	$60.00
☐	two month	$450.00	$225.00
☐	three month	$1,020.00	$510.00
☐	four month	$1,590.00	$795.00
☐	five month	$2,160.00	$1,080.00
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Eddie E. Scott
Agent for Applicant(s)
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Date: May 8, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peter Krulevitch, et al.
Serial No.: 09/992,248
Filed: 11/16/2001
For: Flexible Electrode Array for Artificial Vision

Attorney Docket No.: IL-10896
Group Art Unit: 3762
Examiner: Jeffery R. Jastrzab

Commissioner for Patents
Alexandria, VA 22313-1450

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Kathy Raymond

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Peter Krulevitch, et al.	Docket No. :	IL-10896
Serial No. :	09/992,248	Art Unit :	3762
Filed :	11/16/2001	Examiner :	Jeffery R. Jastrzab
For :	FLEXIBLE ELECTRODE ARRAY FOR ARTIFICAL VISION		

Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANTS' BRIEF (37 C.F.R. § 1.192)

This brief is submitted in support of appellants' notice of appeal from the decision of the Examiner, mailed March 23, 2006 finally rejecting claims 1, 2, 6-12, 14, 15, 18-21, and 25-28 of the subject application. Appellants' notice of appeal was mailed April 3, 2006.

One copy of the brief is being transmitted per 37 C.F.R. § 41.37.

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TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is:

The Regents of the University of California and the United States of America as represented by the United States Department of Energy (DOE) by virtue of an assignment by the inventor as duly recorded in the Assignment Branch of the U.S. Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

The application as originally filed contained claims 1-56.

Claims 3-5, 16, 17, 22-24, and 29-31 are canceled.

Claims 32-56 are withdrawn from consideration.

Claims 1, 2, 6-12, 14, 15, 18-21, and 25-28 are rejected.

The claims on appeal are claims 1, 2, 6-12, 14, 15, 18-21, and 25-28.

Claims 1, 2, 6-12, 14, 15, 18-21, and 25-28 on appeal are reproduced in the Appendix.

IV. STATUS OF AMENDMENTS

There have been no amendments filed subsequent to the Final Rejection mailed March 23, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' claimed invention provides an electrode array for an artificial vision system that can help restore vision to people left totally or partially blind by retinal degeneration or other retinal diseases.

Appellants' claimed electrode array comprises "a conformable substrate composed entirely of a flexible and stretchable polymer ... micro-stimulator electrodes embedded in said conformable substrate ... said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes." FIG. 8B of Appellants' drawings reproduced below illustrates the electrode array. The polymer substrate 11 is composed entirely of a flexible and stretchable polymer poly(dimethylsiloxane). The conformable substrate 11 provides the support for the micro-stimulator electrodes 12a.

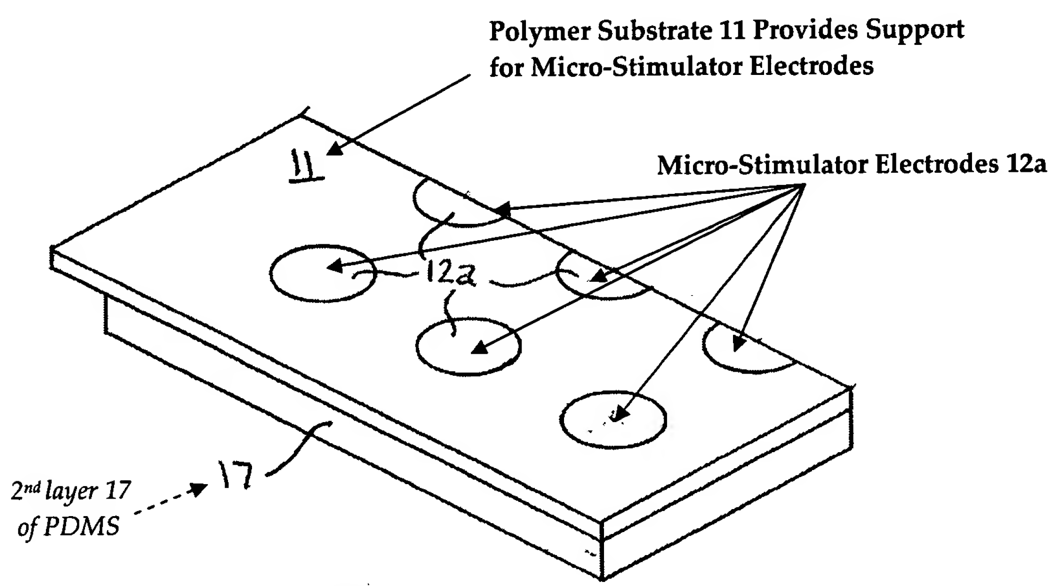

FIG. 8B

Appellants' artificial vision system is illustrated in Appellants' FIG. 13 reproduced below. A video camera captures an image 51. A device sends the image via cable connection, a laser or RF signal 52 into a patient's eye 53. Electronics 54 within the eye 53 receive the image signal 51 and send it to the electrode array 55. The implant stimulates retinal neurons 56. The retinal neurons transmit a signal to be decoded to the brain 57.

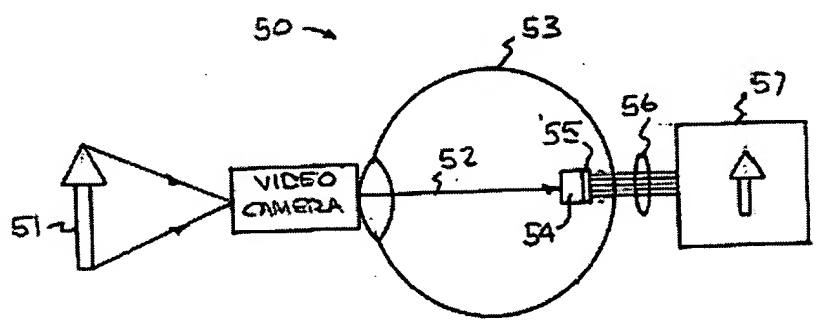

FIG. 13

Appellants are providing a concise explanation of (1) the subject matter defined in each of the independent claims 1, 18, and 25 involved in the appeal and (2) the subject matter defined in each of the dependent claims 6, 8, 9, 12, 19, 21, and 28 argued separately.

The concise explanation refers to the specification by page and line number and to the drawings by reference characters.

The claims do not include means plus function or step plus function.

There are three independent claims, claims 1, 18, and 25, involved in the appeal.

There are seven dependent claims argued separately involved in the appeal. The seven dependent claims argued separately are claims 6, 8, 9, 12, 19, 21, and 28.

The elements of Appellants' independent claims 1, 18, and 25 on appeal are "read on" Appellants' original specification as follows:

Claim 1	Specification & Drawings
An electrode array for an artificial vision system that is adapted to transfer an image signal to a retina having tissue containing cells wherein the electrode array is adapted to provide connection to the tissue containing the cells, comprising:	An electrode array for an artificial vision system for receiving an image signal representing an image and transferring said image signal to a retina ... (Page 31, lines 3-4) The system uses a substrate with embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13)

Claim 1 (Continued)	Specification & Drawings
a conformable substrate composed entirely of a flexible and stretchable polymer that has the ability to conform to various shapes of the tissue, and	a polymer substrate 11 that has the ability to conform to various shapes of tissue. (Page 18, lines 13-14) In another embodiment the polymer is an elastomer that is flexible and stretchable. (Page 19, lines 3-4)
micro-stimulator electrodes embedded in said conformable substrate composed entirely of a flexible and stretchable polymer for contacting the tissue wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) and said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes.	The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. The fact that the device is flexible and can conform to the shape of the patient's retina is highly advantageous. (Page 23, lines 12-16)

Claim 18	Specification & Drawings
An electrode array for an artificial vision system for receiving an image signal representing an image and adapted for transferring the image signal to a retina having tissue containing cells wherein the electrode array is adapted to provide connection to the tissue containing the cells, comprising:	An electrode array for an artificial vision system for receiving an image signal representing an image and transferring said image signal to a retina … (Page 31, lines 3-4) The system uses a substrate with embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13)
an electrode array including a conformable polymer substrate, said polymer substrate being a flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) and having the ability to conform to the shape of the retina, and	a polymer substrate 11 that has the ability to conform to various shapes of tissue. (Page 18, lines 13-14) In another embodiment the polymer is an elastomer that is flexible and stretchable. (Page 19, lines 3-4)

Claim 18 (Continued)

micro-stimulator electrodes embedded in said conformable polymer substrate wherein said conformable substrate composed entirely of a flexible and stretchable polymer provides the support for said micro-stimulator electrodes.

Specification & Drawings

The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. The fact that the device is flexible and can conform to the shape of the patient's retina is highly advantageous. (Page 23, lines 12-16)

Claim 25

An electrode array implant for an artificial vision system for receiving an image signal representing an image and adapted to transmit the image into an eye and to a retina having tissue containing cells, comprising:

Specification & Drawings

An electrode array for an artificial vision system for receiving an image signal representing an image and transferring said image signal to a retina … (Page 31, lines 3-4) embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13)

an implant adapted to be connected to the eye and the retina comprising a flexible polymer substrate, said flexible polymer substrate consisting of poly(dimethylsiloxane) and being flexible and stretchable and having the ability to conform to the shape of the retina, and

The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. The fact that the device is flexible and can conform to the shape of the patient's retina is highly advantageous. (Page 23, lines 12-16)

micro-stimulator electrodes embedded in said flexible polymer substrate comprising poly(dimethylsiloxane) wherein said conformable substrate comprising poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes.

The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. The fact that the device is flexible and can conform to the shape of the patient's retina is highly advantageous. (Page 23, lines 14-16)

The elements of Appellants' dependent claims 6, 8, 9, 12, 19, 21, and 28 argued separately are "read on" Appellants' original specification as follows:

Claim 6	Specification & Drawings
The electrode array of claim 1, wherein said micro-stimulator electrodes embedded in said conformable substrate composed entirely of a flexible and stretchable polymer for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells for transferring the image signal to the retina.	The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. (Page 23, lines 12-15) The system uses a substrate with embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13)

Claim 8	Specification & Drawings
Claim 2. The electrode array of claim 1, including conductive leads connected to said micro-stimulator electrodes. Claim 8. The electrode array of claim 2, wherein the artificial vision system includes a device for transferring a visual image signal and wherein said micro-stimulator electrodes for contacting the tissue are adapted for stimulating the cells and said conductive leads are connected to the device for transferring a visual image signal.	The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. (Page 23, lines 12-15)

Claim 9	Specification & Drawings
The electrode array of claim 8, wherein said micro-stimulator electrodes for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue.	The conformable PDMS substrate 42 has embedded microstimulator electrodes 41. The microstimulators 41 connect the implant to the retina. The electrodes 41 stimulate the retina with a pattern of electrical pulses based on the sensed image signal. (Page 24, lines 14-17)

Claim 12

Claim 10. The electrode array of claim 9, wherein said substrate is composed of a flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) is a flexible and stretchable polymer of a shape and size that has the ability to conform to the shape of said retina tissue.
Claim 11. The electrode array of claim 10, wherein said conductive leads and said micro-stimulator electrodes are adapted to transmit the image signal to the cells in the retina tissue.
Claim 12. The electrode array of claim 11, wherein said micro-stimulator electrodes for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons.

Specification & Drawings

The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. (Page 23, lines 12-15)

The system uses a substrate with embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13)

The implant 54 stimulates retinal neurons. (Page 22, lines 9-10)

Claim 19

19. The electrode array for an artificial vision system of claim 18, wherein said micro-stimulator electrodes are embedded in said flexible and stretchable polymer substrate composed entirely of poly(dimethylsiloxane) and said micro-stimulator electrodes are adapted to contact the retina and are adapted to have the image signal stimulate the cells in the retina.

Specification & Drawings

The implant 54 includes an electrode array of poly(dimethylsiloxane) (PDMS, a form of silicone rubber) for the substrate. The substrate includes embedded electrodes and conductive leads for directly stimulating cells in the retina and transmitting a visual image. (Page 23, lines 12-15)

Claim 21	Specification & Drawings
The electrode array for an artificial vision system of claim 20, wherein said micro-stimulator electrodes are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons.	The system uses a substrate with embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13) The implant 54 stimulates retinal neurons. (Page 22, lines 9-10)

Claim 28	Specification & Drawings
The artificial vision system of claim 27, wherein said micro-stimulator electrodes are adapted to transmit the signal representing the image to the cells in the retina and wherein the cells are retinal neurons.	The system uses a substrate with embedded electrodes and conductive leads for directly stimulating cells. (Page 7, lines 11-13) The implant 54 stimulates retinal neurons. (Page 22, lines 9-10)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection mailed March 23, 2006 states three (3) separate grounds of rejection. The three (3) grounds of rejection are summarized below.

Grounds of Rejection #1 - Claims 6, 8, 9, 12, 19, 21, and 28 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Grounds of Rejection #2 – Claim 19 was rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Grounds of Rejection #3 - Claims 1, 2, 6-12, 14, 15, 18-21, and 25-28 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell et al reference in view of the Pinchuk reference (U.S. Patent No. 6,458,157) as stated on page 3 of the Final Rejection mailed March 23, 2006.

VII. ARGUMENT

Appellants present arguments directed to the three (3) separate grounds of rejection in the Final Rejection mailed March 23, 2006. The arguments are set out under separate headings for each separate grounds #1 through #3.

Argument Directed to Grounds of Rejection #1 – Claims 6, 8, 9, 12, 21, and 28 were rejected under 35 U.S.C. 112, second paragraph, in the Final Rejection mailed March 23, 2006 as being indefinite for specific reasons itemized in the Final Rejection.

Claim 6

In the Final Rejection mailed March 23, 2006, claim 6 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with the stated reason being it "lack(s) sufficient structure to further limit the invention."

Claim 6 is a dependent claim depending from claim 1 and adds the following structural limitation to claim 1:

> "wherein said micro-stimulator electrodes embedded in said conformable substrate composed entirely of a flexible and stretchable polymer for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells for transferring the image signal to the retina."

Appellants argue that claim 6 does include sufficient structure to further limit the invention. Claim 6 includes the additional structural limitations "micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses."

Claim 8

In the Final Rejection mailed March 23, 2006, claim 8 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with the stated reason being

it "claims elements of the combination (device) but only the electrode array is being claimed per the preamble."

Appellants argue that claim 8 on appeal is not indefinite. Claim 8 adds structural limitations to the electrode array. The fact that claim 8 also adds structural limitations to the combination (device) does not make claim 8 indefinite.

Claim 8 depends from claim 2 and claim 2 adds the structural element "including conductive leads connected to said micro-stimulator electrodes." Claim 8 together with claim 2 specifies the following additional limitations relating to the electrode array:

> "including conductive leads connected to said micro-stimulator electrodes .... said conductive leads are connected to the device for transferring a visual image signal."

Appellants argue that claim 8 is not indefinite and that claim 8 includes the addition of structural limitations to the electrode array.

<u>Claim 9</u>

In the Final Rejection mailed March 23, 2006, claim 9 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with the stated reason being it "lack(s) sufficient structure to further limit the invention."

Claim 9 is a dependent claim depending from claim 8. Claim 8 is a dependent claim depending from claim 2. Claim 2 is a dependent claim depending from claim 1. Claim 9 adds the following structural limitation to claims 1, 2, and 8:

> "wherein said micro-stimulator electrodes for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue."

Appellants argue that claim 9 does include sufficient structure to further limit the invention. Claim 9 includes the additional structural limitations "micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue."

Claim 12

In the Final Rejection mailed March 23, 2006, claim 12 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with the stated reason being it "lack(s) sufficient structure to further limit the invention."

Claim 12 is a dependent claim depending from claim 11. Claim 11 is a dependent claim depending from claim 10. Claim 10 is a dependent claim depending from claim 11. Claim 10 is a dependent claim depending from claim 9. Claim 9 is a dependent claim depending from claim 8. Claim 8 is a dependent claim depending from claim 2. Claim 2 is a dependent claim depending from claim 1. Claim 12 adds the following structural limitation to claims 1, 2, 8, 9, 10, and 11:

> "wherein said micro-stimulator electrodes for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons."

Appellants argue that claim 12 does include sufficient structure to further limit the invention. Appellants argue that claim 12 does include structural limitations by specifying "micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons," which are structural limitations.

Claim 21

In the Final Rejection mailed March 23, 2006, claim 21 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with the stated reason being it "lack(s) sufficient structure to further limit the invention."

Claim 21 is a dependent claim depending from claim 20. Claim 20 is a dependent claim depending from claim 18. Claim 21 adds the following structural limitation to claims 18 and 20:

> "wherein said micro-stimulator electrodes are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons."

Appellants argue that claim 21 does include sufficient structure to further limit the invention. Claim 21 depends from claim 20 and claim 20 adds the structural element "including conductive leads connected to said micro-stimulator electrodes" and claim 21 does include structural limitations by specifying that the "micro-stimulator electrodes are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons," which are structural limitations.

Claim 28

In the Final Rejection mailed March 23, 2006, claim 28 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with the stated reason being "the preamble refers to the combination (device) but only the electrode array is being claimed per claim 27, thus making the scope inconsistent."

Appellants argue that claim 28 on appeal is not indefinite. Claim 28 adds structural limitations to the electrode array. The fact that claim 28 also adds

structural limitations to the combination (device) does not make claim 8 indefinite and does not make the scope inconsistent.

Claim 28 depends from claim 27 and claim 27 depends from claim 25. Claim 28 adds the following structural limitations:

> "including conductive leads connected to said micro-stimulator electrodes wherein said conductive leads and said micro-stimulator electrodes are adapted to transmit the signal representing the image to the cells in the retina."

Claim 28 together with claim 27 and 25 specifies specific limitations relating to the electrode array "said micro-stimulator electrodes are adapted to transmit the signal representing the image to the cells in the retina the cells are retinal neurons."

<u>**Argument Directed to Grounds of Rejection #2**</u> – Claim 19 was rejected in the Final Rejection mailed March 23, 2006 as allegedly being directed to non-statutory subject matter under 35 U.S.C. 101, with the stated reason being "the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body which renders these claims non-statutory."

Claim 19 is a dependent claim depending from claim 18. Claim 19 reads as follows:

> 19. The electrode array for an artificial vision system of claim 18, wherein said micro-stimulator electrodes are embedded in said flexible and stretchable polymer substrate composed entirely of poly(dimethylsiloxane) and said micro-stimulator electrodes are adapted to contact the retina and are adapted to have the image signal stimulate the cells in the retina.

Appellants argue that claim 19 does not claim the body. Claim 19 specifies, "said micro-stimulator electrodes are adapted to contact the retina and are adapted to have the image signal stimulate the cells in the retina."

The Final Rejection mailed March 23, 2006 does not cite authority for the rejection that claims reciting, "adapted to contact the retina" and "adapted to have the image signal stimulate the cells in the retina" are directed to non-statutory subject matter under 35 U.S.C. 101. Appellants' legal research does not find any authority for this rejection.

M.P.E.P section 706.03(a) dealing with rejections under 36 U.S.C. 101 gives "examples of subject matter not patentable under the statute follow: B. Naturally Occurring Article Similarly, a thing occurring in nature, which is substantially unaltered, is not a 'manufacture.' A shrimp with the head and digestive tract removed is and an example."

Appellants' claim 19 does not claim the body. Claim 19 only recites that the micro-stimulator electrodes are adapted to contact the retina and are adapted to have the image signal stimulate the cells in the retina.

Argument Directed to Grounds of Rejection #3 - The invention defined by Appellants' claims 1, 2, 6-12, 14, 15, 18-21, and 25-28 on appeal is unobvious over any combination of the Primary Edell et al reference (U.S. Patent No. 5,476,494) and the Secondary Pinchuk reference (U.S. Patent No. 5,741,331). The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

Differences Between Appellants' Invention and References

The differences between the references and Appellants' invention defined by claims 1, 2, 6-12, 14, 15, 18-21, and 25-28 on appeal includes the fact that the references fails to show elements of Appellants' invention. In particular, the following elements of Appellants' claims are not shown in the references:

> "a conformable substrate composed entirely of a flexible and stretchable polymer ... wherein said conformable substrate is composed entirely of poly(dimethylsiloxane)"
>
> "said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes."

The Edell et al Reference (U.S. Patent No. 5,476,494)

The Edell et al reference shows a cantilever with an encapsulation layer 24 of very flexible and soft silicone material encapsulating the cantilever. A copy of FIG. 2B of the Edell et al reference is provided below with inserts added that identify the cantilever and the encapsulation layer 24.

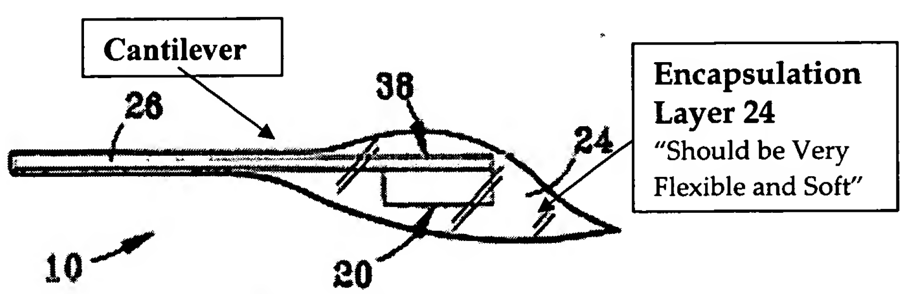

FIG. 2B

The fact that the Edell et al reference shows a cantilever is provided by the statements in the Edell et al reference which describes the cantilever, "Examples of materials suitable for the cantilever include silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials." (Col. 4, lines 44-47 of Edell et al)

The fact that the Edell et al reference shows a very flexible and soft encapsulation layer 24 is provided by the statements in the Edell et al reference, "As shown in FIGS. 2a, 2b, and 3, the encapsulation layer 24 surrounds the cantilever structure 40. This layer, preferably of silicone material, should be very flexible and soft."

Edell et al Does Not Show Appellants' "Substrate" Claim Element

The Edell et al reference shows a very flexible and soft encapsulation layer 24 whereas Appellants' claim element is a "substrate that provides the support for said micro-stimulator electrodes."

In the Edell et al reference the encapsulation layer 24 strictly covers and protects the cantilever. The Edell et al reference encapsulation layer 24 does not provide support as defined in Appellants' claims.

A "substrate" is not the same as an "encapsulation layer." The two structural elements perform different functions. Appellants' "substrate" claim element provides support; whereas, the Edell et al reference "flexible and soft encapsulation layer" covers and protects what is encapsulated.

The Edell et al Encapsulation Layer Does Not Provide Support

The Edell et al reference "encapsulation layer 24" is described in Col. 5, lines 62-67 as follows: "As shown in FIGS. 2a, 2b, and 3, the encapsulation layer 24 surrounds the cantilever structure 40. This layer, preferably of silicone material, should be very flexible and soft, and should extend beyond the edges of the cantilever structure 40 by an amount equal to at least its thickness, and more preferably 4-5 times its thickness."

The description of Edell et al reference encapsulation layer 24 "should be very flexible and soft" shows that it does not provide support.

Prior to Appellants' claimed invention, silicone material was not known as a material used for a substrate support for an electronic device. "Silicone" was best known as the material used in breast implants.

Since the Edell et al reference encapsulation layer 24 does not provide support, the Edell et al reference does not show Appellants' claim elements, "a conformable substrate composed entirely of a flexible and stretchable polymer ... wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) ... said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes"

Appellants' claims include the structural limitations that the "substrate composed entirely of a flexible and stretchable polymer provides the support for said micro-stimulator electrodes." In the Edell et al reference the cantilever provides the support. The Edell et al reference cantilever is not a polymer that provides the support for said micro-stimulator electrodes as defined in Appellants' claims.

The Secondary Pinchuk Reference (U.S. Patent No. 5,741,331)

The Secondary Pinchuk reference shows "biostable elastomeric polymers having quaternary carbons." The Secondary Pinchuk reference is described as: "The present invention generally relates to implantable prostheses and the like which are formed in a manner to substantially prevent cracking, crazing or degradation thereof when they are implanted or otherwise subjected to degradation conditions. A medical prosthesis or the like according to this invention includes a polyolefinic elastomeric triblock star or linear copolymer where the backbone comprises alternating units of quaternary and secondary carbons which will not crack or degrade when subjected to implantation for substantial time periods during which other types of polymers would crack or degrade." (Col. 1, lines 6-16 Pinchuk reference)

The Secondary Pinchuk reference is not directed to an electronic device and does not take the problems of electronic devices into consideration. The Pinchuk reference does not show Appellants' claim elements, "a conformable substrate composed entirely of a flexible and stretchable polymer … wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) … said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes"

Can Be No Combination of Ebell et al and Pinchuk That Would Show Appellants' Claimed Invention

In the Ebell reference the very flexible and soft silicone encapsulation layer 24 is strictly used for encapsulation and does not show Appellants' claim elements. The secondary Pinchuk reference does not show Appellants' claim elements.

Since both the Primary Ebell et al reference and the Secondary Pinchuk reference fail to show the elements of Appellants' claimed invention, there can be no combination of the two references that would support a 35 USC §103(a) rejection.

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir.1991). The combination of the Ebell et al and Pinchuk references proposed in the Final Rejection mailed March 23, 2006 would not be "obvious." Further, the combination of the Ebell et al and Pinchuk references proposed in the Final Rejection mailed March 23, 2006 does not show Appellants' claimed invention. Accordingly, the Final Rejection mailed March 23, 2006 does not support a rejection of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 under 35 USC 103.

Secondary Considerations

Alternatively, Appellants present arguments rebutting the grounds of rejection #3 under 35 U.S.C. 103(a) that Appellants' claims are allegedly "obvious" over the Edell et al reference in view of the Pinchuk reference.

Appellants' claimed invention has obtained commercial success and recognition by peers. These secondary considerations should be taken into account in deciding the obviousness or nonobviousness of Appellants' claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 on appeal.

Commercial Success

An October 14, 2004 article in *ScienceDaily LLC*, titled, "Livermore Scientists Join DOE Consortium In Partnering With Private Company To Develop Artificial Retina" includes the following statements: "A Department of Energy consortium of national laboratories including Livermore and universities today signed an agreement with Second Sight Medical Products Inc. to jointly develop technology that could restore sight to those who have lost vision later in life. The Cooperative Research and Development Agreement (CRADA) allows Second Sight Medical Products Inc. of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project."

"Engineers from LLNL's Center for Micro- and Nanotechnology specifically are developing a flexible silicone implant (microelectrode array) that sits on the surface of the retina. The electrode array can contact delicate retinal tissue without damaging it."

"LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina."

The article is available at the website: "www.nanoinvestornews.com" and a copy of the article Copyright © 1995-2005 *ScienceDaily LLC* is attached. The article was also published as a New Release on October 14, 2004 by the Lawrence Livermore National Laboratory.

The Secondary consideration that the Cooperative Research and Development Agreement (CRADA) allows Second Sight Medical Products Inc. of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project should be taken into account in deciding the obviousness or nonobviousness of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28. The fact that Second Sight Medical Products Inc. of Sylmar, Calif. has obtained a limited exclusive license under Appellants' claimed

invention shows commercial success and supports the nonobviousness of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28.

Recognition by Peers and Commercial Success

An October 14, 2004 New Release by the U. S. Department of Energy, titled "DOE Labs, Universities and Second Sight Partner to Speed Development of 'Artificial Retina' Restoring Sight through Science," includes the following statements:

"The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see."

"Lawrence Livermore National Laboratory is developing a thin, flexible implant that can conform to the curved shape of the retina."

A copy of the U. S. Department of Energy News Release is attached.

The Secondary considerations in the October 14, 2004 News Release by the U. S. Department of Energy, titled "DOE Labs, Universities and Second Sight Partner to Speed Development of 'Artificial Retina' Restoring Sight through Science" and the October 14, 2004 article in *ScienceDaily LLC*, titled, "Livermore Scientists Join DOE Consortium In Partnering With Private Company To Develop Artificial Retina" should be taken into account in deciding the obviousness or nonobviousness of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28.

The fact that (1) Energy Secretary Spencer Abraham described the project as, "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see," (2)

"LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina," and (3) the Cooperative Research and Development Agreement (CRADA) allows Second Sight Medical Products Inc. of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project shows recognition by peers and commercial success and supports the nonobviousness of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28.

It is respectfully requested that claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 on appeal be allowed.

Respectfully submitted,

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CLAIMS APPENDIX

1. An electrode array for an artificial vision system that is adapted to transfer an image signal to a retina having tissue containing cells wherein the electrode array is adapted to provide connection to the tissue containing the cells, comprising:

a conformable substrate composed entirely of a flexible and stretchable polymer that has the ability to conform to various shapes of the tissue, and

micro-stimulator electrodes embedded in said conformable substrate composed entirely of a flexible and stretchable polymer for contacting the tissue wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) and said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes.

2. The electrode array of claim 1, including conductive leads connected to said micro-stimulator electrodes.

6. The electrode array of claim 1, wherein said micro-stimulator electrodes embedded in said conformable substrate composed entirely of a flexible and stretchable polymer for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells for transferring the image signal to the retina.

7. The electrode array of claim 2, wherein the artificial vision system includes a device for transferring a visual image signal and wherein said conductive leads are connected to the device for transferring a visual image signal.

8. The electrode array of claim 2, wherein the artificial vision system includes a device for transferring a visual image signal and wherein said micro-stimulator electrodes for contacting the tissue are adapted for stimulating the

cells and said conductive leads are connected to the device for transferring a visual image signal.

9. The electrode array of claim 8, wherein said micro-stimulator electrodes for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue.

10. The electrode array of claim 9, wherein said substrate is composed of a flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) is a flexible and stretchable polymer of a shape and size that has the ability to conform to the shape of said retina tissue.

11. The electrode array of claim 10, wherein said conductive leads and said micro-stimulator electrodes are adapted to transmit the image signal to the cells in the retina tissue.

12. The electrode array of claim 11, wherein said micro-stimulator electrodes for contacting the tissue are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons.

14. The electrode array of claim 1, wherein said flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) is an elastomer.

15. The electrode array of claim 1, wherein said flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) is an elastomer that is flexible.

18. An electrode array for an artificial vision system for receiving an image signal representing an image and adapted for transferring the image signal to a retina having tissue containing cells wherein the electrode array is adapted to provide connection to the tissue containing the cells, comprising:

an electrode array including a conformable polymer substrate, said polymer substrate being a flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) and having the ability to conform to the shape of the retina, and

micro-stimulator electrodes embedded in said conformable polymer substrate wherein said conformable substrate composed entirely of a flexible and stretchable polymer provides the support for said micro-stimulator electrodes.

19. The electrode array for an artificial vision system of claim 18, wherein said micro-stimulator electrodes are embedded in said flexible and stretchable polymer substrate composed entirely of poly(dimethylsiloxane) and said micro-stimulator electrodes are adapted to contact the retina and are adapted to have the image signal stimulate the cells in the retina.

20. The electrode array for an artificial vision system of claim 18, including conductive leads connected to said micro-stimulator electrodes wherein said conductive leads and said micro-stimulator electrodes are adapted to transmit the signal representing the image to the cells in the retina.

21. The electrode array for an artificial vision system of claim 20, wherein said micro-stimulator electrodes are micro-stimulator electrodes adapted to stimulate with a pattern of electrical pulses useful for stimulating the cells in the retina tissue and wherein the cells are retinal neurons.

25. An electrode array implant for an artificial vision system for receiving an image signal representing an image and adapted to transmit the image into an eye and to a retina having tissue containing cells, comprising:

an implant adapted to be connected to the eye and the retina comprising a flexible polymer substrate, said flexible polymer substrate consisting of poly(dimethylsiloxane) and being flexible and stretchable and having the ability to conform to the shape of the retina, and

micro-stimulator electrodes embedded in said flexible polymer substrate comprising poly(dimethylsiloxane) wherein said conformable substrate comprising poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes.

26. The electrode array for an artificial vision system of claim 25, wherein said micro-stimulator electrodes are embedded in said flexible polymer substrate consisting of poly(dimethylsiloxane) and are adapted to contact the retina and the signal representing the image is adapted to stimulate the cells in the retina.

27. The electrode array for an artificial vision system of claim 25, including conductive leads connected to said micro-stimulator electrodes wherein said conductive leads and said micro-stimulator electrodes are adapted to transmit the signal representing the image to the cells in the retina.

28. The artificial vision system of claim 27, wherein said micro-stimulator electrodes are adapted to transmit the signal representing the image to the cells in the retina and wherein the cells are retinal neurons.

EVIDENCE APPENDIX

Two documents are enclosed.

ScienceDaily LLC October 14, 2004 article titled, "Livermore Scientists Join DOE Consortium In Partnering With Private Company To Develop Artificial Retina."

News Release by the U. S. Department of Energy October 14, 2004, titled "DOE Labs, Universities and Second Sight Partner to Speed Development of 'Artificial Retina' Restoring Sight through Science."

RELATED PROCEEDINGS APPENDIX

There are no Related Proceedings.

Livermore Scientists Join DOE Consortium In Partnering With Private Company To Develop Artificial Retina

CHICAGO, Ill. - A Department of Energy consortium of national laboratories including Livermore and universities today signed an agreement with Second Sight Medical Products Inc. to jointly develop technology that could restore sight to those who have lost vision later in life.

The Cooperative Research and Development Agreement (CRADA) allows Second Sight Medical Products Inc. of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project.

"The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see. This agreement between the DOE laboratories and the private sector will facilitate transfer of many aspects of DOE technology to a clinical device that has the potential of restoring sight to millions of blind individuals.

An artificial retina could restore vision to millions of people suffering from eye diseases such as macular degeneration (the leading cause of blindness in people over 60), retinitis pigmentosa (the leading cause of blindness in people under 50), or those who are legally blind due to the loss of photoreceptor function.

Lawrence Livermore partnered with four other national laboratories, three universities and Second Sight on the project.

Engineers from LLNL's Center for Micro- and Nanotechnology specifically are developing a flexible silicone implant (microelectrode array) that sits on the surface of the retina. The electrode array can contact delicate retinal tissue without damaging it.

The implantable retinal prosthesis is based on a system that converts a video camera signal into a stimulation pattern that is applied directly to the intra-ocular retinal surface. This is referred to as an epiretinal implant - the device is in contact with the surface of the retina. Visual signals are captured by a small video camera in the eyeglasses of the blind person and processed through a microcomputer worn on a belt.

Although the device will not restore full vision, it is expected to provide enough optical resolution for patients to read and recognize fine shapes.

LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina.

"PDMS has the look and feel of thin plastic food wrap," said Livermore's principal investigator, Courtney Davidson. "Yet it's biocompatible, making it a good candidate material for long-term implants."

Partners in the project include Oak Ridge, Argonne, Sandia and Los Alamos national laboratories, the University of California, Santa Cruz, the University of Southern California Doheny Eye Institute and North Carolina State University.

Project leader Dr. Mark Humayun of USC has shown that electrical stimulation of the viable retinal cells can result in visual perception. These findings helped spark the worldwide effort to develop a retinal prosthesis device.

The first patient to receive a prototype implant in 2002 was able to see large letters and to differentiate between a cup, a plate and a knife after being blind for more than 50 years. To date, six volunteers have received implants of a micro-electronic device that rests on the surface of the retina to perform the function of normal photoreceptive cells.

The artificial retina technology was featured today at the department's "What's Next Expo," an event designed to showcase the newest, most innovative, cutting-edge scientific and technological advances to interest young people in pursuing careers in math and science.

Second Sight was founded in 1998 to create a retinal prosthesis to provide sight to patients blinded from outer retinal degenerations.

Founded in 1952, Lawrence Livermore National Laboratory is a national security laboratory, with a mission to ensure national security and apply science and technology to the important issues of our time. Lawrence Livermore National Laboratory is managed by the University of California for the U.S. Department of Energy's National Nuclear Security Administration.

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U.S. DEPARTMENT OF
ENERGY

October 14, 2004

DOE Labs, Universities and Second Sight Partner to Speed Development of "Artificial Retina"
Restoring Sight through Science

CHICAGO, IL – In an effort to speed the design and development of an artificial retina that could potentially help millions of people blinded by retinal diseases, Secretary of Energy Spencer Abraham announced today that five Department of Energy (DOE) national laboratories, a private company and three universities have signed agreements to form a research partnership.

The goal of the agreements signed today is to advance the science, technology and clinical success of the field of artificial sight using the facilities and resources of DOE's national laboratories.

At today's announcement in Chicago, the first patient to receive a prototype implant in 2002 described what it was like being able to "see" large letters and to differentiate between a cup, a plate and a knife after being blind for over 50 years. To date, six volunteers have received implants of a micro-electronic device that rests on the surface of the retina to perform the function of normal photoreceptive cells. The artificial retina technology was featured at the department's "What's Next Expo," an event designed to showcase the newest, most innovative, cutting-edge scientific and technological advances to interest young people in pursuing careers in math and science.

"The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Secretary Abraham said. "This project is one such example where biology, physics, and engineering have joined forces to deliver a capability that will enable blind people to see. This agreement between the DOE laboratories and the private sector will facilitate transfer of many aspects of DOE technology to a clinical device that has the potential of restoring sight to millions of blind individuals."

The agreements allow Second Sight Medical Products Inc. based in Sylmar, Calif., to obtain a limited exclusive license for inventions developed during the artificial retina project. Under the research agreements, the institutions will jointly share intellectual property rights and royalties from their research. This will speed progress by freeing the researchers to share details of their work with their collaborators.

The artificial retina could help those blinded by age-related macular degeneration or retinitis pigmentosa where neural wiring from the eye to brain is intact, but the eyes lack photoreceptor activity. The artificial retina is a device that captures visual signals and sends them to the brain in the form of electrical impulses. The device is a miniature disc that contains an electrode array that can be implanted in the back of the eye to replace a damaged retina. Visual signals are captured by a small video camera in the eyeglasses of the blind person and processed through a microcomputer worn on a belt. The signals are transmitted to the electrode array in the eye. The array stimulates optical nerves, which then carry a signal to the brain. The first prototype implants contain 16 electrodes. The next prototype, with 50-100 electrodes, is in preclinical trials. The project's "next generation" device would have 1,000 electrodes and hopefully would allow the user to see images.

The Department of Energy-supported project is a collaboration of DOE national laboratories, universities and the private sector:

Oak Ridge National Laboratory and the University of Southern California Doheny Eye Institute are leading the multi-laboratory effort. Oak Ridge's research includes developing better electrodes and fabrication techniques and studying the long-term stability of the device once it is implanted.

Argonne National Laboratory scientists, in collaboration with Second Sight, are using their patented ultrananocrystalline diamond technology to make the implant biocompatible with the surrounding ocular tissue.

Lawrence Livermore National Laboratory is developing a thin, flexible implant that can conform to the curved shape of the retina.

A **Los Alamos National Laboratory** team is developing advanced optical imaging techniques. They are providing a better understanding of how the prosthesis works, by mapping the interaction between the brain and retina.

Sandia National Laboratories researchers are developing advanced electrodes using MEMS (micro-electro-mechanical systems) research.

The University of Southern California Doheny Eye Institute provides medical direction of the project and performs clinical testing of the implants.

North Carolina State University is performing electrical and thermal modeling of the device to help determine how much energy can be used to stimulate the remaining non-diseased cells.

University of California, Santa Cruz work includes wireless communication technology to provide the link between the camera and the implant.

Second Sight created the prototype device that is currently in testing. Second Sight will integrate DOE technology into product designs that will eventually move on to clinical trials.

Using the unique resources of the DOE national laboratories in materials sciences, microfabrication, microelectrode construction, photochemistry and computer modeling, the project's goal is to construct the device, capable of restoring vision, with materials that will last for the lifetime of a blind person. Although images will initially be captured by a camera housed in an eyeglass frame, researchers hope eventually to develop a completely implanted system for this purpose. DOE's effort is focused on developing high-grade microelectrodes and testing their long term biological effects, developing electrode and platform materials that are pliable and will last a lifetime within the eye, constructing a completely wireless device for clinical use and performing the computational modeling of long-term retinal stimulation.

The Energy Department's Office of Science plans to fund the artificial retina project at $20 million over the next three years. The department funds the project as part of its medical applications technology program. DOE and its predecessor agencies have been in the forefront of imaging sciences including clinical imaging in nuclear medicine and imaging atoms at synchrotron light sources. The National Institutes of Health and the National Science Foundation are also supporting the project.